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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/483,837	01/17/2000	Shubh D. Sharma	70025-9902-11	8919

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EXAMINER

WESSENDORF, TERESA D.

ART UNIT PAPER NUMBER

1639

DATE MAILED: 07/27/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/483,837

Applicant(s)

SHARMA, SHUBH D.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-41, 43-50 and 52-81 is/are pending in the application.
- 4a) Of the above claim(s) 35-40 and 60-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41, 43-50 and 52-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 63-81 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these newly added claims are drawn to the metals which was not originally presented or prosecuted.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 63-81 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of Claims

Claims 35-41, 43-50 and 52-81 are pending in the application.

Claims 35-40 and 60-81 are withdrawn from consideration as being directed to a non-elected invention.

Claims 42 and 51 have been cancelled.

Claims 41, 43-50 and 52-59 are under consideration.

Oath/Declaration

The oath or declaration is defective for reasons set forth in the last Office action, 2/14/01.

Response to Arguments

Applicant states that a copy of a new oath/declaration is attached as Attachment A and applicant will file a supplemental declaration upon allowance of claims.

In reply, Attachment A is not on file. Further, it is unclear as to the necessity of filing a Supplemental declaration, if Attachment A presents a new oath/declaration.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 41, 43-50 and 52-59 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specifically asserted utility or a well established utility for reasons set forth in the last Office action.

Response to Arguments

Applicant argues that the utility of the library is not for screening. Rather, to select and identify metallopeptides and metallo-constructs that bind to the different recited receptors of interest.

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In response, is this simply a difference in semantics? For selecting and identifying for a metalloptides and metallo-constructs is nothing but screening i.e., the libraries are screened such that a specific mettaloptides can be identified. The identification of which involves binding to a receptor.

Applicant argues that PTO has consistently recognized the inherent utility of combinatorial libraries per se, and has issued numerous patens wherein the claims are directly solely to combinatorial libraries.

In reply, each case is treated on its own merits.

Applicant argues that the use of a combinatorial library is well known in the art, citing e.g., page 9, line 18 up to page 15, line 6.

In response, these references pertain to a specific library of defined structures as opposed to the instant undefined library structure.

Claims 41, 43-50 and 52-59 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specifically asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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See the response above.

Claim Rejections - 35 USC § 112, first paragraph

Claims 41, 43-50 and 52-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific library that binds to rhenium metal, does not reasonably provide enablement for any type of combinatorial library with at least three residues, two of which form a metal-ion binding domain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record.

Response to Arguments

Applicant argues that bioassays and various method of screening and elucidating a "hit" are well known in the art of combinatorial chemistry, citing e.g., page 9, line 18-page 15, line 6.

In reply, applicant's arguments as to the known screening method is not commensurate in scope with the claims which recite a compound i.e., library. Be it as it may the cited section reveals a method that is specific for the library at hand, and

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not for any library of any defined structure. A "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials". University of California v. Eli Lilly and Col, 43 USPQ 2d 1398, 1405(1997), quoting Fiers V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993)[The claims at issued in University of California v. Eli Lilly defined the invention by function of the claimed DNA (encoding insulin)]. See also University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003).

Claims 41, 43-50 and 52-59, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 41, 43-50 and 52-59, as amended, which recites "...unique selection or sequence occurs in the one or more amino acid residues... at the N or C-terminus of the metal ion-binding backbone...." is not supported in the as-filed specification.

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MPEP 714.02 recites that applicants point out where specifically support for the new limitations appear.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of

35U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41, 43-50 and 52-59, as applied to the amended claims, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

In view of the amendments to the claims and applicant's arguments, the rejection of the claims under this statute has been overcome-in part. The claims that are maintained are addressed below.

Response to Arguments

1). It is argued that the language "synthesized on solid phase" refers to solid phase bound library.

In reply, if this is so, it is suggested that applicants positively recite said solid phase bound library, to avoid any ambiguity.

Applicant argues that "unique" is as clear as is permitted in the English language. Unique may be either a unique selection

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(e.g., amino acid sequences GGCA vs. GGCT, where each is clearly unique with respect to the other.)

In reply, as stated by applicants the English language permits a wide or indefinite means or characterization of a unique selection. It is however unclear in the sense as it applies to amino acid sequences. Therefore, the metes and bounds of said uniqueness is not clearly set forth in the specification or claims.

Claims 41, 43-50, 52-59, as amended are rejected as follows:

A. Claim 41, for example is inconsistent. Component (a) recites a sequence between three that appears inconsistent with (i) and (ii) if the sequence is only three-residue peptide. If there are two residues that bind to the backbone for complexation, then where, how and what is the third residue? The claims provide for confusion and ambiguity. It is not clear if in fact binding occurs, especially in the absence of positive showing in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41, 45, 46, 47, 50, 54, 55, 59 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Francis et al [(J.Am. Chems.Soc.) (I) for reasons advanced in the last Office action.

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Response to Arguments

Applicant argues that Francis was published 18 September 1996, which is after the priority (08/660,697) filing date of 6/5/1996.

In reply, in the absence of the oath or declaration claiming said priority the rejection is proper.

Claims 41, 43-50, 52-59 are rejected under 35 U.S.C. 103(a) as being obvious over Kay et al (5,498,538) for reasons of record.

Response to Arguments

Applicant argues that Kay teaches a phage display library. Claim 41 is to a library wherein members are bound to solid phase.

In response, attention is drawn to applicant's disclosure which recites that "...Libraries produced by genetic engineering tools are largely composed of peptide molecules, and are similar to solid-phase libraries in the sense that the peptide molecules are displayed or attached on the surface of vectors or bacteriophages used for their production...."

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Applicant further argues that Kay teaches only use of His groups and provides that Cys may not be employed in the library.

In reply, Kay at col.48, line 66 up to col. 49, line 25, as cited by applicants, does not exclude cys in fact provides data with cys and his. Kay recites that cys residues participate in Z coordinate by protein in vivo, citing Berg. Thus, the suggested teachings of Kay that cys can be used suffice the finding of obviousness.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

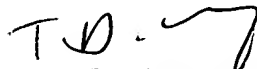
This application contains claims 35-40 and 60-81 are drawn to a non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0812. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
July 24, 2004